

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED  
PHARMACEUTICAL PRODUCTS  
R&D, INC., NORTON  
(WATERFORD) LTD., and TEVA  
PHARMACEUTICALS USA, INC.

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF  
NEW YORK, LLC, AMNEAL  
IRELAND LIMITED, AMNEAL  
PHARMACEUTICALS LLC, and  
AMNEAL PHARMACEUTICALS  
INC.

Defendants.

Civil Action No. 23-cv-20964-SRC-  
MAH

**[PROPOSED] ORDER  
GRANTING DEFENDANTS'  
MOTION FOR JUDGMENT ON  
THE PLEADINGS PURSUANT  
TO FED. R. CIV. P. 12(c) AS TO  
COUNTERCLAIMS 1-5**

**THIS MATTER** having come before the Court by Defendants Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc. (collectively, “Defendants”) seeking an Order granting judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) as to Counts 1-5 of Defendants’ Counterclaims (ECF No. 12); and the Court having considered the submissions and arguments of the parties; and for good cause shown;

**IT IS on this \_\_\_\_\_ day of \_\_\_\_\_, 2024,**

**ORDERED** that Defendants’ Motion for Judgment on the Pleadings Pursuant to Fed. R. Civ. P. 12(c) as to Counterclaims 1-5 is hereby **GRANTED**; and it is further

**ORDERED** that judgment is entered in Defendants’ favor as to Counts 1-5 of Defendants’ Counterclaims (ECF No. 12); and it is further

**ORDERED** that U.S. Patent Nos. 8,132,712, 9,463,289, 9,808,587, 10,561,808, and 11,395,889 (collectively, the “Asserted Patents”) were not and are not properly listed in the Orange Book in connection with NDA No. 021457 for ProAir® HFA (the “ProAir® HFA NDA”); and it is further

**ORDERED** that, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii), Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Limited, and Teva Pharmaceuticals USA, Inc. must delete or withdraw all of the Asserted Patents from the Orange Book in connection with the ProAir® HFA NDA and, in compliance with 21 C.F.R. § 314.53(f)(2)(i), submit to the Food and Drug Administration an amendment to that effect to the ProAir® HFA NDA.

**SO ORDERED**

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HONORABLE STANLEY R. CHESLER, U.S.D.J.